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EXAMINER

HUTSON, RICHARD G

ART UNIT PAPER NUMBER

1652

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/641,319

Applicant(s)

SLATER ET AL.

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 22-47 is/are pending in the application.
- 4a) Of the above claim(s) 31-39, 41-43 and 45-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-30, 40 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other: _____

DETAILED ACTION

Claims 22-47 are at issue and are present for examination.

Applicant's election with traverse of Group I, Claims 22-30, 40 and 44 in Paper No. 17 is acknowledged. The traversal is on the following ground(s). Applicants submit that the present claims are copied from U.S. Patent No. 5,939,301 in order to preserve the right to provoke an interference proceeding with the patentees of the '301 patent. Applicants further submit that claims from both Groups 1 and 2 were issued in the '301 patent and since the examiner has the discretion to waive the current restriction, such should be done in order to be more economical for both parties involved as well as the patent office. Applicants further submit that the prior art in these cases is well understood, having been assessed in both the '301 patent prosecution and in the parent applications of the present application.

Applicants arguments are not found persuasive. In response to applicants first argument, as was previously stated in the parent applications parent case, 09/385,986, which is now abandoned for failure to respond to an action, Applicants are reminded "potential interferences" in no way effect a restriction requirement. In response to applicants second argument, applicants that the prior art in these cases is well understood, having been assessed in both the '301 patent prosecution and in the parent applications of the present application, applicants are reminded that the present application is being conducted by a different examiner then the '301 case or the parent application of the present application, 08/484,661 and that each application is a separate entity such that a complete review of the prior art must be made for each

application. Further applicants are reminded that "Restriction is only proper if it can be shown that: (1) the claims belong to separate classifications; (2) a different field of search would be required; or (3) the claims have a separate status in the art... One of these three criteria must be established to support a restriction." It is acknowledged that the previous restriction requirement listed each of the groups as being classified in class 435, subclass 194, although it should be pointed out that the search for each of the separate inventions is not coextensive and would involve the search of subclasses unnecessary for the search of the other. For instance a search for the invention of group II would include a search of class 536, subclass 23.2, which would not be unnecessary for a search of group I. Thus it would be unduly burdensome to search and examine the claims of Groups I and II.

The requirement is still deemed proper and is therefore made FINAL.

Claims 31-39, 40, and 45-47 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 17.

Specification

The disclosure is objected to because of the following informalities:

Figures 2 and 3 each list amino or nucleic acid sequences which do not have associated with them a sequence identifier (i.e. SEQ ID NO).

2422.02 The Requirement for Exclusive Conformance; Sequences Presented in Drawing Figures

... It should be noted, though, that when a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief

Description of the Drawings.

On page 36, line 21-22 there appear to be amino acid sequences which should also include an associated SEQ ID NO.

Appropriate correction is required.

Claim Objections

Claims 29 and 30 are objected to because of the following informalities: Claims 29 and 30 each recite "The composition of Claim 23, wherein said mutant polymerase...". Claim 23 is drawn to a composition comprising a mutant DNA polymerase..." A number of other claims dependent on claim 23, such as claims 24-28 each recite "The composition of Claim 23, wherein said mutant DNA polymerase...". It is suggested that applicants maintain consistency in the claims as much as possible, such as amending claims 29 and 30 to recite "The composition of Claim 23, wherein said mutant DNA polymerase..."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-30, 40 and 44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 22, 23 and 27-30 are directed to a composition comprising all possible purified non-naturally occurring or mutant DNA polymerases or fragments thereof, capable of DNA synthetic activity, derived from *Thermococcus neapolitana*, wherein said mutant DNA polymerase comprises one or more amino acid substitutions or deletions (claims 27 and 28), wherein said mutant polymerase is devoid of an N-terminal 5'-3' exonuclease domain or the 283 N-terminal amino acids of native *Thermotoga neapolitana* DNA polymerase (claims 29 and 30). Claims 24-26, 40 and 44 are directed to a composition comprising all possible mutant *Thermotoga neapolitana* DNA polymerases, wherein said mutation reduces a 3'-5' or 5'-3' exonuclease activity (claims 24 and 25), wherein said mutant DNA polymerase is a Pol I-type DNA polymerase (claims 40 and 44), or reduces discrimination against dideoxynucleotides (claim 26). The claimed genus is a large variable genus with potentiality of comprising many different DNA polymerases mutants many of which have not yet been identified.

The specification, however, does not provide a sufficient number of species encompassed by the claims to be representative of the claimed genus. It is acknowledged that while the specification teaches a Tne DNA polymerase, having the amino acid sequence of SEQ ID NO: 2 which is not encompassed by the claimed genus, as well as a number of members of the claimed genus which is encompassed by those mutations previously known for other highly homologous polymerases which

result in a reduction or elimination of either 3'-5' exonuclease activity and 5'-3' exonuclease activity these species are not representative of the claimed genus which includes all isolated mutant Tne DNA polymerases with any modification which reduces 3'-5' exonuclease activity or 5'-3' exonuclease activity, said modifications including those previously identified as well as those yet to be discovered. The claimed genus is infinitesimally large compared to that applicants have shown possession of. The specification further suggests that if the Tne DNA polymerase has 3'-5' or 5'-3' activity, this activity may be reduced or eliminated by mutating the Tne DNA polymerase gene using such mutations as point mutations, frame shift mutations, deletions and insertions. There is no disclosure of any particular structure to function/activity relationship in the claimed genus. The specification also fails to describe any representative species of these polymerases by any identifying structural characteristics or properties other than having reduced 3'-5' exonuclease activity, 5'-3' exonuclease activity or reduced discrimination against dideoxynucleotides for which no predictability of structure is apparent.

Given this lack of additional representative species as encompassed by the above claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Claim 30 is further rejected because it is unclear where the recitation "...devoid of the 283-N-terminal amino acids..." of the claimed polymerase has support in the specification as originally filed, therefore this recitation is considered new matter.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 22 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Chatterjee et al. (U.S. Patent No: 5,912,155).

Chatterjee et al. teach a composition comprising a thermostable Pol-I type DNA polymerase from *Thermotoga neapolitana* (Tne) and they teach that this DNA polymerase is capable of DNA synthetic activity. Chatterjee et al. teach the isolation and cloning of the *T. neapolitana* polymerase gene into the plasmid pSport1. Furthermore it is believed that the naturally occurring Tne DNA polymerase taught by Chatterjee et al. is capable of both 3'-5' and 5'-3' exonuclease activity and has a specific activity of approximately 100,000 units/mg. It is acknowledged that the DNA polymerase taught by Chatterjee et al. may not be considered "non-naturally-occurring, however, as Chatterjee et al. also teach fragments of the taught DNA polymerase, these fragments anticipate claims to a fragment of both a naturally-occurring DNA polymerase

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as well as a non-naturally-occurring DNA polymerase as many of these fragments are the same molecules.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-30, 41 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chatterjee et al. (U.S. Patent No: 5,912,155) as applied to claims 22, 23, 25-27, 41, 42, and 44-47 above, and further in view of Erlich et al. (Science 252:1643-1651, June 1991).

As discussed above, Chatterjee et al. teach a composition comprising a thermostable Pol-I type DNA polymerase from *Thermotoga neapolitana* (Tne) and they teach that this DNA polymerase is capable of DNA synthetic activity. Chatterjee et al. further suggest that the 3'-5' exonuclease activity may be reduced or eliminated by mutating the Tne DNA polymerase such that the region of the gene encoding the 3'-5' domain is deleted.

Erlich et al. review recent advances in the polymerase chain reaction including the modification of the polymerase enzymes used in these methods so as to effect the reactions results. Erlich et al. specifically teach the use thermostable DNA polymerases from a number of thermostable organisms. Erlich et al. further teach removal of the 3'

to 5' exonuclease activity is desirable so that the polymerase can be used in sequence-specific priming reactions because this activity removes the mismatched base at the 3'-end of the primer. Erlich et al. further teach that a genetically engineered variant of Taq DNA polymerase lacking the 5' to 3' exonuclease permits efficient amplification of long fragments.

One of ordinary skill in the art would have been motivated to mutate the Tne DNA polymerase taught by Chatterjee et al. by deleting the 3'-5' exonuclease domain as suggested by Chatterjee et al. in order to mutate this polymerase so that it can be used in sequence-specific priming reactions as taught by Erlich et al. Further, one of ordinary skill in the art would have been motivated to mutate the Tne DNA polymerase taught by Chatterjee et al. by deleting the 5' to 3' exonuclease domain in order to mutate this polymerase so that it can be used in PCR reactions in which the permits efficient amplification of long fragments is the desired goal, as taught by Erlich et al. The reasonable expectation of success for the removal of either the 3'-5' or 5'-3' exonuclease domains of the Tne DNA polymerase comes from the high degree of knowledge in the art as reviewed by Erlich et al. who describes such mutations of previously isolated DNA polymerases.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

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1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-30, 41 and 44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S.

Patent No. 6,001,645. An obvious type double patenting rejection is appropriate where conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Claims 22-30, 41 and 44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S.

Patent No. 6,001,645. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims 1-3 drawn to the Tne derived DNA polymerase variants having an amino acid sequence selected from the group consisting of SEQ ID NOs: 8, 16, 19, 23, 26, 29, 33 and 35 anticipate claims 22-30, 41 and 44 of the instant application.

Remarks

No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

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August 8, 2003